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PATENT APPLICATION
Docket No.: 16861-00019

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Inventor: Stephen M. ZAPPALA

Reissue Application No.: 10/734,070 Filed Date: March 30, 2001

Confirmation No. 1261 Group: 1614 Examiner: Donna A. Jagoe

For: PREEMPTIVE ANALGESIC AGENT AND METHODS OF USE

**Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450**

Sir:

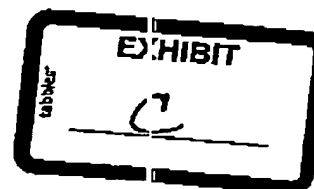
DECLARATION OF STEPHEN M. ZAPPALA UNDER 37 C.F.R. §1.112

I, Stephen M. Zappala, hereby make the following declaration:

1. I am the inventor of the invention described in U.S. patent application 10/734,070 filed March 30, 2001 ("the '070 application"), U.S. patent application 09/656,150 filed on September 6, 2000 ("the '050 application"), and U.S. provisional patent application 60/152,718, filed on September 7, 1999 ("the '718 application").

2. The disclosure of the '718 application included a description of a patient study of penile regional anesthetic nerve block for urological surgery featuring the intracavernosal instillation of a mixture of lidocaine HCl 1% (Abbott Laboratories, North Chicago, IL) and bupivacaine HCl 0.25% (Astra USA, Westborough, MA). Seventy-four men (ages 16-85) underwent ambulatory penile surgery including circumcision, penile biopsy, partial penectomy and cystoscopy. A tourniquet was applied at midshaft of the phallus and a 21 gauge butterfly hypodermic needle was introduced into the right cavernosal body, and the correct position of the needle was verified by the gentle aspiration of desaturated blood. The anesthetic agent was a mixture of 10 cc of 0.25% bupivacaine combined with 20 cc of 1% lidocaine to make a total volume of 30 cc. An artificial penile erection was produced as the 30 cc of anesthetic agent was instilled through the 21 gauge hypodermic needle into the right

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cavernosal body. Total anesthesia was achieved approximately five minutes after instillation of the anesthetic agent; hemostasis was obtained after the tourniquet was removed.

3. All seventy-four patients underwent surgery without requiring conversion to general anesthesia. No significant intraoperative or post-operative bleeding occurred. The intracavernosal anesthetic was not associated with cardiac arrhythmias, CNS disturbances or plaque formation at the injection site. Post-operative analgesia included acetaminophen in most cases.

4. Adequate analgesia for surgery was achieved rapidly, and without the risks associated with inhalation anesthesia and spinal anesthesia.

5. The technique did not produce the distortion of penile anatomy found with subcutaneous infiltration of a local anesthetic to produce block of the dorsal nerve.

6. The penile block produced by the instillation of the anesthetic agent provided the post-operative analgesic benefits of preceptive analgesia.

7. I further declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 101 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the above-identified application or any patent issuing thereon.

Respectfully Submitted,

Date: 7/12/06.
Stephen M. Zappala

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